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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,938	08/21/2001	Pathiraja A. Gunatillake	1207.008US1	7489
21186 7590 06/08/2007 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER SERGENT, RABON A	
			ART UNIT 1711	PAPER NUMBER
			MAIL DATE 06/08/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/933,938

Applicant(s)

GUNATILLAKE ET AL.

Examiner

Rabon Sergent

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-79,81-108,111,112 and 117-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-79,81-108,111,112 and 117-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 63-79, 81-108, 111, 112, and 117-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher et al. ('627) or WO 98/13405 or JP 4-248826, each in view of Li et al. ('724) and Ohtaki et al. ('085).

The primary references disclose the production of polysiloxane-polyurethane (urea) polymers having enhanced biocompatibility wherein active hydrogen group containing polysiloxanes are combined with additional active hydrogen compounds, such as polyethers or polycarbonates, and the resulting mixtures are reacted with polyisocyanates to yield polymers having enhanced characteristics. It is noted that Szycher et al. and JP 4-248826 disclose the use of hydroxyl functional polysiloxanes, as well as, amine functional polysiloxanes.

3. While none of the primary references disclose the specific use of an amine functional siloxane as a chain extender and WO 98/13405 fails to disclose the use of an amine functional

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siloxane soft segment, Li et al. specifically teach the use of amine functional polysiloxane compounds, which overlap applicants' claimed soft segment and hard segment compounds, in the production of biocompatible polyureas and polyurethane ureas having improved physical and mechanical properties. Furthermore, Ohtaki et al. disclose the use of amino functional tetraorganodisiloxanes as modifying reactants within polyurethanes.

4. Therefore, since applicants' claimed amine functional polysiloxanes were known reaction constituents for polyurethaneurea and since they were known to bestow improved properties, including improved biocompatibility, to urethanes, it would have been *prima facie* obvious to utilize them as reactants, such as chain extenders and/or soft segment reactants, within the compositions of the primary references, so as to arrive at the instant invention.

5. Applicants' response of March 22, 2007 has been considered; however, it is not seen that applicants' instant response has adequately addressed the issues previously set forth. Despite applicants' arguments, the position is maintained for the aforementioned reasons that the secondary references serve to render obvious the use of compounds that correspond to applicants' claimed hard and soft segment compounds as reactants for polyurethaneureas having improved properties. The position is again taken that applicants' response fails to appreciate the teachings of the secondary references. As aforementioned, Li et al. disclose the use of amine functional siloxane compounds that overlap applicants' claimed soft segment and hard segment compounds as reactants within polyurethaneureas and further disclose that the resulting polymers display biocompatibility and improved physical and mechanical properties. Though Li et al. refer to the use of the siloxanes in the production of soft segments, this disclosure is not seen to be controlling in view of the disclosed molecular weight or length of the siloxane segments.

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Since the distinction between hard segments and soft segments resides primarily in the molecular weight or length of the respective segments, and since Li et al. disclose compounds having molecular weight ranges or lengths that encompass both the hard and soft segments of the instant invention, it follows that Li et al. serve to teach that their siloxanes may be employed as the instant hard and soft segment compounds in the production of biocompatible polymers.

Furthermore, Ohtaki et al. provide additional teaching that low molecular weight amine functional siloxanes may be employed as chain extenders within polyurethanes.

6. Consonant with applicants' request of March 22, 2007, applicants' 37 CFR 1.132 declaration, filed July 6, 2006, has again been considered; however, the declaration continues to be insufficient to overcome the prior art rejection for the following reasons. Firstly, it is unclear what composition within WO 98/13405 has been utilized as a comparative example. Applicants' must clearly set forth the composition, as it pertains to the reference, so that the examiner can ascertain exactly how the comparative example relates to the example of the instant invention and how the comparative example is representative of the prior art. In response to this issue, it appears that applicants have argued that the comparative composition is identical to the instant composition except that no amine siloxane chain extender is present. This response is insufficient to establish the exact composition of the comparative example, because it would seem that there must be other differences within the formulation than simply deleting a component in order to maintain such characteristics as the required stoichiometry. Secondly, applicants have provided no commentary on the additional primary references relied upon, in that no explanation has been provided describing how the comparative example of WO 98/13405 is relevant to the teachings of the additional primary references. Thirdly, comparisons against Li

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et al. are not particularly relevant, since the Li et al. reference is not considered to be the most relevant prior art. Comparisons should be made against the compositions of the primary references or rationale must be provided explaining why the relied upon comparative example is considered to be representative of the closest available prior art. Fourthly, the relied upon example of the invention is not commensurate in scope with the claims. Applicants have argued that the example of the instant invention relates to the composition of claim 104; however, the composition of the example is not commensurate in scope with claim 104 in terms of component species and quantitative amounts. Furthermore, the relied upon example of the invention is even less commensurate in scope with the remaining independent claims, all subject to the same prior art rejection. For example, claim 63 requires the use of a macrodiamine; however, the relied upon example does not utilize a macrodiamine. It has been held that to overcome a reasonable case of *prima facie* obviousness, a given claim must be commensurate in scope with any showing of unexpected results. *In re Greenfield*, 197 USPQ 227. Furthermore, it has been held that a limited showing of criticality is insufficient to support a broadly claimed range. *In re Lemin*, 161 USPQ 288. *In re Kulling*, 14 USPQ2d 1056. Given these tenets, applicants' showings are insufficient to justify removal of the prior art rejection. Accordingly, applicants have failed to establish that the respective use of the claimed soft segment reactants and chain extenders yield an unexpected result, relative to the teachings of the relied upon references.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

R. Sergent
June 5, 2007


RABON SERGENT
PRIMARY EXAMINER